

Attorney's Docket No.: 09531-016002

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gary L. Nelsestuen

Serial No.: 10/031,005

Art Unit: 1646

Examiner: Unknown

Filed Title

: October 29, 2001

MODIFIED VITAMIN K-DEPENDENT POLYPEPTIDES

TECH CENTER 1600/2900

Commissioner for Patents Washington, DC 20231

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The following correspondence relating to this application is enclosed for filing:

- Information Disclosure Statement (1 page); 1.
- 2. Form PTO-1449 (4 pages); and
- 3. A Return Postcard.

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Respectfully submitted,

Monica McCormick Graham, Ph.D.

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INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO-1449.

Under 35 USC §120, this application relies on the earlier filing date of application serial number PCT/US00/11416, filed on April 28, 2000, which claims priority to application serial number 09/302,239, filed on April 29, 1999. The references listed on the attached form PTO-1449 were submitted to and/or cited by the Patent Office in the prior application and, copies therefore, are not provided in this application.

This statement is being filed within three months of the filing date of the application or before the receipt of a first Office action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

28/02

Monica McCormick Graham, Ph.D.

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Sheet	1_	of	4

Substitute Form PTO-13 (Modified) 男.S. Department of Commerce Patent and Trademark Office **Bieclosure Statement** Information

Attorney's Docket No. 09531-016002

Application No. 10/031,005

by Applicant (Use several sheets if necessary)

Applicant Gary L. Nelsestuen

Filing Date

Group Art Unit

(37 CFR §1.98(b))

October 29, 2001

1646

	U.S. Patent Documents						
Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,093,317	03/03/92	Lewis et al.			
	AB	5,258,288	11/02/93	Wydro et al.			
	AC	5,288,629	02/22/94	Berkner		RECEI	VED
	AD	5,504,064	04/02/96	Morrissey et al.		JUN 1 2	
	AE	5,516,640	05/14/96	Watanabe et al.	TEC		
	AF	5,580,560	12/03/96	Nicolaisen et al.	TEC	H CENTER	600;2900
	AG	5,788,965	08/04/98	Berkner et al.			
	AH	5,817,788	10/06/98	Berkner et al.			
	AI	5,824,639	10/20/98	Berkner			
	AJ	5,833,982	11/20/98	Berkner et al.			
	AK	5,837,843	11/17/98	Smirnov et al.			
	AL	5,847,085	12/08/98	Esmon et al.			
	AM	5,861,374	01/19/99	Berkner et al.			
	AN	6,017,882	01/25/00	Nelsestuen		·	

	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Trans Yes	lation No
	AO	0 296 413 A2	12/28/88	EPO				
	AP	0 354 504 A2	02/14/90	ЕРО				
	AQ	WO 99/20767	04/29/99	PCT				

	Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner	Desig.	Danis and			
Initial	ID	Document			
	AR	Arnlijots et al., "Prevention of experimental arterial thrombosis by topical administration of active			
<u></u>		site-inactivated factor VIIa," J. Vasc. Surg., 1997, 25(2):341-346			
	AS	Bauer, "Treatment of factor VII deficiency with recombinant factor VIIa," <u>Haemostasis</u> , 1996, 26(Suppl. 1):155-158			
· · · · · · · · · · · · · · · · · · ·					
	AT	Broze et al., "Monoclonal anti-human factor VII antibodies. Detection in plasma of a second protein antigenically and genetically related to factor VII," J. Clin. Invest., 1985, 76:937-946			
	AU	Choudhri et al., "Targeted Inhibition of Intrinsic Coagulation Limits Cerebral Injury in Stroke without Increasing Intracerebral Hemorrhage," J. Exp. Med., 1999, 190:91-99			

Examiner Signature

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet <u>2</u> of <u>4</u>

U.S. Department of Commerce Application No. 10/031,003 Attorney's Docket No. Substitute Form PTO-1449 (Modified) 09531-016002 JUN 1 2 2002 Applicant Information Disclosure Statement Gary L. Nelsestuen by Applicant (Use several sheets if necessary) GLECHI OENTER 1600/2900 Filing Date October 29, 2001 (37 CFR §1.98(b))

	Other D	ocuments (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
THE STATE OF THE S	AV	Christiansen et al., "Hydrophobic Amino Acid Residues of Human Anticoagulation Protein C that Contribute to its Functional Binding to Phospholipid Vesicles," <u>Biochemistry</u> , 1995, 34:10376-10382
	AW	Dackiw et al., "Prevention of endotoxin-induced mortality by antitissue factor immunization," <u>Arch. Surg.</u> , 1996, 131:1273-1278
	AX	Dahlback, "Inherited Thrombophilia: Resistance to Activated Protein C as a Pathogenic Factor of Venous Thromboemolism," <u>Blood</u> , 1995, 85:607-614
	AY	Esmon et al., "Isolation of a membrane-bound cofactor for thrombin-catalyzed activation of protein C," J. Biol. Chem., 1982, 257:859-864
	AZ	Evans, Jr. and Nelsestuen, "Importance of <i>cis</i> -Proline 22 in the Membrane-Binding Conformation of Bovine Prothrombin," <u>Biochemistry</u> , 1996, 35:8210-8215
	AAA	Evans and Nelsestuan, "Importance of Cis-Proline 22 and the Aromatic Stack (Residues 41-45) for Prothrombin-Membrane Binding," <u>Protein Sci.</u> , 1996, 5(Suppl. 1):163, Abstract #606-S
	ABB	Felgner et al., "Lipofection: a highly efficient, lipid-mediated DNA-transfection procedure," Proc. Natl. Acad. Sci. USA, 1987, 84:7413-7417
	ACC	Fiore et al., "The biochemical basis for the apparent defect of soluble mutant tissue factor in enhancing the proteolytic activities of factor VIIa," <u>J. Biol. Chem.</u> , 1994, 269:143-149
	ADD	Freedman et al., "Identification of the phospholipid binding site in the vitamin K-dependent blood coagulation protein factor IX," J. Biol. Chem., 1996, 271(27):16227-16236
	AEE	Furie and Furie, "The molecular basis of blood coagulation," Cell, 1988, 53:505-518
	AFF	Han et al., "Isolation of a protein Z-dependent plasma protease inhibitor," Proc. Natl. Acad. Sci. USA, 1998, 95:9250-9255
	AGG	He et al., "Expression and functional characterization of chimeras between human and bovine vitamin-K-dependent protein-S-defining modules important for the species specificity of the activated protein C cofactor activity," <u>Eur. J. Biochem.</u> , 1995, 227:433-440
	АНН	Hedner et al., "Recombinant Activated Factor VII in the Treatment of Bleeding Episodes in Patients with Inherited and Acquired Bleeding Disorders," <u>Transfus. Med. Rev.</u> , 1993, 7:78-83
	AII	Hope et al., "Production of Large Unilamellar Vesicles by a Rapid Extrusion Procedure. Characterization of Size Distribution, Trapped Volume and Ability to Maintain a Membrane Protential," Biochem. Biophys. Acta, 1985, 812:55-65
	AJJ	Hoskins et al., "Cloning and characterization of human liver cDNA encoding a protein S precursor," Proc. Natl. Acad. Sci. USA, 1987, 84:349-353
	AKK	Huang, <u>Biochemistry</u> , 1969, 8:344-352
	ALL	Humphries et al., "Chemical methods of protein synthesis and modification," <u>Curr. Opin.</u> <u>Biotechnol.</u> , 1991, 2(4):539-543
	AMM	Lu and Nelsestuen, "Dynamic Features of Prothrombin Interation with Phospholipid Vesicles of Different Size and Composition: Implications for Protein – Membrane Contact," <u>Biochemistry</u> , 1996, 35:8193-8200
	ANN	Lu and Nelsestuen, "The prothrombinase reaction: "mechanism switching" between Michaelis- Menten and non-Michaelis-Menten behaviors," <u>Biochemistry</u> , 1996, 35:8201-8209
	A00	Matsubara et al., "A receptor tyrosine kinase, Sky, and its ligand Gas 6 are expressed in gonads and support primordial germ cell growth or survival in culture," <u>Dev. Biol.</u> , 1996, 180:499-510

Examiner Signature	Date Considered				
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with					
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Substitute Disclosure Form (PTO-1449)

Sheet <u>3</u> of <u>4</u>

Substitute Form PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office

Attorney's Docket No. Applicatio **Po** 10/031,005 09531-016002 JUN 1 2 2002 Applicant

Information Disclosure Statement by Applicant (Use several sheets if necessary)

Gary L. Nelsestuen

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(37 CFR §1.98(b))

Filing Date October 29, 2001 1646

	Other D	Occuments (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
miliar	APP	Mayer et al., "Prothrombin Association with Phospholipid Monolayers," <u>Biochemistry</u> , 1983, 22(2):316-321
	AQQ	McDonald et al., "Comparison of Naturally Occurring Vitamin K-dependent Proteins: Correlation of Amino Acid Sequences and Membrane Binding Properties Suggests a Membrane Contact Site," Biochemistry, 1997, 36:5120-5127
	ARR	McDonald et al., "Ionic Properties of Membrane Association by Vitamin K-Dependent Proteins: The Case for Univalency," <u>Biochemistry</u> , 1997, 36(50):15589-15598
	ASS	Morrissey et al., "Quantitation of Activated Factor VII Levels in Plasma Using a Tissue Factor Mutant Selectively Deficient in Promoting Factor VII Activation," <u>Blood</u> , 1993, 81(3):734-744
	ATT	Muir et al., "The chemical synthesis of proteins," Curr. Opin. Biotechnol., 1993, 4(4):420-427
	AUU	Nakagaki et al., "Initiation of the Extrinsic Pathway of Blood Coagulation: Evidence for the Tissue Factor Dependent Autoactivation of Human Coagulation Factor VII," <u>Biochemistry</u> , 1991, 30:10819-10824
	AVV	Nelsestuen and Suttie, "Properties of Asialo and Aglycoprothrombin," <u>Biochem. Biophys. Res.</u> Commun., 1971, 45:198-203
	AWW	Nelsestuen et al., "Equilibria Involved in Prothrombin- and Blood Clotting Factor X-Membrane Binding," Biochemistry, 1977, 16(19):4164-4171
	AXX	Nicolaes et al., "A prothrombinase-based assay for detection of resistance to activated protein C," Thromb. Haemost., 1996, 76:404-410
	AYY	Nicolaisen et al., "Immunological aspects of recombinant factor VIIa (rFVIIa) in clinical use," Thromb. Haemost., 1996, 76:200-204
	AZZ	Perera et al., "Trans-cis Isomerization of Proline 22 in Bovine Prothrombin Fragment 1: A Surprising Result of Structural Characterization," <u>Biochemistry</u> , 1998, 37:10920-10927
	AAAA	Persson and Nielsen, "Site-directed mutagenesis but not gamma-carboxylation of Glu-35 in factor VIIa affects the association with tissue factor," FEBS Letters, 1996, 385(3):241-243
	ABBB	Petersen et al., "Quenching of the amidolytic activity of one-chain tissue-type plasminogen activator by mutation of lysine-416," <u>Biochemistry</u> , 1990, 29:3451-3457
	ACCC	Ratcliffe et al., "The Importance of Specific γ-Carboxyglutamic Acid Residues in Prothrombin," <u>J.</u> <u>Biol. Chem.</u> , 1993, 268(32):24339-24345
	ADDD	Resnick and Nelsestuen, "Prothrombin-Membrane Interaction. Effects of Ionic Strength, pH, and Temperature," Biochemistry, 1980, 19(13):3028-3033
	AEEE	Rezaie and Esmon, "The function of calcium in protein C activation by thrombin and the thrombin-thrombomodulin complex can be distinguished by mutational analysis of protein C derivatives," <u>J. Biol. Chem.</u> , 1992, 267:26104-26109
	AFFF	Schmidel et al., "Oranization of the Human Protein S Genes," J. Biol. Chem., 1990, 29(34):7845-7852
	AGGG	Schulman et al., "Feasibility of using recombinant factor VIIa in continuous infusion," Thromb. Haemost., 1996, 75(3):432-436
	АННН	Schwalbe et al., "Protein Structural Requirements and Properties of Membrane Binding by γ-Carboxyglutamic Acid-containing Plasma Proteins and Peptides," J. Biol. Chem., 1989, 264:20288-20296
	AIII	Seshadri et al., "Differences in the Metal Ion Structure between Sr- and Ca-Prothrombin Fragment 1," <u>Biochemistry</u> , 1994, 33:1087-1092

Examiner Signature Date Considered

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Sheet <u>4</u> of <u>4</u>

Substitute Form PTO-1449 (Modified)

(37 CFR §1.98(b))

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Information Disclosure Statement
by Applicant
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Applicant
Gary L. Nelsestuen

JUN 1 2 2002

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Filing Date
October 29, 2001

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	Other D	ocuments (include Author, Title, Date, and Place of Publication)
Examiner	Desig.	
Initial	ID	Document
	AJJJ	Shah et al., "Manipulation of the membrane binding site of vitamin K-dependent proteins: Enhanced biological function of human factor VII," Proc. Natl. Acad. Sci. USA, 1998, 95(8):4229-4234
	AKKK	Shen et al., "Enhancing the Activity of Protein C by Mutagenetis to Improve the Membrane-Binding Site: Studies Related to Proline 10," <u>Biochemistry</u> , 1997, 36(51):16025-16031
, , , , , , , , , , , , , , , , , , ,	ALLL	Shen et al., "Enhancement of Human Protein C Function by Site-directed Mutagenesis of the γ-Carboxyglutamic Acid Domain," J. Biol. Chem., 1998, 273(47):31086-31091
	АМММ	Smirnov et al., "A Chimeric Protein C Containing the Prothrombin Gla Domain Exhibits Increased Anticoagulant Activity and Altered Phospholipid Specificity," <u>J. Biol. Chem.</u> , 1998, 273(15):9031-9040
	ANNN	Sorensen et al., "Incorporation of an active site inhibitor in factor VIIa alters the affinity for tissue factor," J. Biol. Chem., 1997, 272(18):11863-11868
	A000	Thariath et al., "Highly conserved residue arginine-15 is required for the Ca ²⁺ -dependent properties of the γ-carboxyglutamic acid domain of human anticoagulation Protein C and activated Protein C," Biochem. J., 1997, 322:309-315
	APPP	Thomsen et al., "Pharmacokinetics of recombinant factor VIIa in the rat – a comparison of bio-, immuno- and isotope assays," Thromb. Haemost., 1993, 70(3):458-464
	AQQQ	Vallette et al., "Construction of mutant and chimeric genes using the polymerase chain reaction," Nucleic Acids Res., 1989, 17(2):723-733
	ARRR	Vrana et al., "Expression of tissue factor in tumor stroma correlates with progression to invasive human breast cancer: paracrine regulation by carcinoma cell-derived members of the transforming growth factor beta family," Cancer Res., 56:5063-5070
	ASSS	Weber et al., "Modifications of Bovine Prothrombin Fragment 1 in the Presence and Absence of Ca(II) Ions," J. Biol. Chem., 1992, 267(7):4564-4569
	ATTT	Wei et al., "Kinetic and Mechanistic Analysis of Prothrombin-Membrane Binding by Stopped-Flow Light Scattering," <u>Biochemistry</u> , 1982, 21:1949-1959
	AUUU	Welsch et al., "Chemical Modification of Prothrombin Fragment 1: Documentation of Sequential, Two-Stage Loss of Protein Function," <u>Biochemistry</u> , 1988, 27:4933-4938
	AVVV	Welsch and Nelsestuen, "Amino-terminal alanine functions in a calcium-specific process essential for membrane binding by prothrombin fragment 1," Biochemistry, 1988, 27:4939-4945
	AWWW	Yan et al., "Characterization and Novel Purification of Recombinant Human Protein C from Three Mammalian Cell Lines," <u>Bio/Technology</u> , 1990, 8:655-661
	AXXX	Zhang et al., "Role of Individual γ-Caboxyglutamic Acid Residues of Activated Human Protein C in Defining its In Vitro Anticoagulant Activity," <u>Blood</u> , 1992, 80(4):942-952
	AYYY	Zhang et al., "The Contributions of Individual γ-Carboxyglutamic Acid Residues in the Calcium-dependent Binding of Recombinant Human Protein C to Acidic Phospholipid Vesicles," J. Biol. Chem., 1993, 268(16):12040-12045
	AZZZ	Zwaal et al., "Lipid-protein interactions in blood coagulation," <u>Biochimica et Biophysica Acta</u> , 1998, 1376:433-453

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